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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,509

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Philippe Chatellard

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EXAMINER

KELLY, ROBERT M

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

02/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,509	Applicant(s) CHATELLARD ET AL.	
	Examiner ROBERT M. KELLY	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and argument of 11/17/08 are entered.

Claims 31-51 are presently cancelled.

Claims 52-75 are newly presented, presently pending, and considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claims 31-51, all rejections and/or objections to such claims are rendered moot, and thus are withdrawn with regard to those claims.

Drawings

In light of the new drawing submission for Figure 1, the objections to the drawings are withdrawn.

To wit, Figure 1 now supplies the proper alignment as described in the specification.

Specification

In light of the amendment to the specification, correcting the sequences of Figure 1 with sequences identifiers in the brief description, the objection to the specification is withdrawn.

Claim Rejections - 35 USC § 112 - clarity

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55, 63, 64 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 recites the limitation "the DNA" in Claim 53. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 recites the limitation "the vector" in Claim 52. There is insufficient antecedent basis for this limitation in the claim.

Claims 63 and 64 each recite the limitation "the vector according to Claim 55. There is insufficient basis for this limitation in the claims.

Claims 63 recites "the DNA sequence coding for a polypeptide of interest". There is insufficient basis for this limitation in the claim.

Claims 63 and 64 recite "insulator(s)", however it is not sufficiently clear whether these claims are referring to the insulator of Claim 1, or some other generically-defined insulator. Hence, the metes and bounds are not clear.

Claims 63-64 are rejected for depending from a rejected parent claim.

Claim 65 recites the limitation "the DNA" in Claim 56. There is insufficient antecedent basis for this limitation in the claim, as Claim 56 has insufficient antecedent basis for the same limitation.

Claims 67 and 68 recite "the first subunit" and "the second subunit". In order to be considered the first and second subunits, they must be first and second with regard to something, otherwise, they are simply subunits. Hence, the metes and bounds of such limitations are not clear. It is suggested that Applicant refer to the first and second subunits without utilizing such

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terminology, and simply state that one subunit is X and the other subunit is Y. However, if Applicant wishes state that one is 5' or 3' to the other, Applicant should also make clear whether it is the RNA or DNA, which may also introduce new matter rejections. Alternatively, if Applicant wishes to state that the subunits are referred to in order of appearance in the multimeric protein, such may also introduce new matter rejections.

Claims 65-68 are rejected for depending from at least one rejected parent claim.

Claim 75 recites that the transfection is stable. However, the scope of such is not clear. Clearly, if it was transfected, it is stable, otherwise it would be digested before it was transfected. Perhaps Applicant is intending to claim, (and this is speculation), that it is integrated, or it replicates, or that the vector enters the nucleus, or that it replicates, or some other limitation, but such is not what Applicant has claimed, and the scope is not clear for its metes and bounds.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56 and 65-68 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for comprising new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 56 claims a generic vector comprising a DNA sequence encoding more than one polypeptide through a polycistronic mRNA. However, at best, support is found in the originally filed specification and claims through the preliminary amendment of 4/19/08, Claim 31(g), which also requires either a UTR, a 3' mRNA end processing sequence, a polyA site, or an IRES.

Claims 65-68 similarly lack support, as the dependencies of the claims have simply been changed by Applicant from what was originally claimed or claimed on the same-day preliminary amendment of 4/19/08.

Moreover, because the claim is by amendment, support must be found in the original filings, and cannot rely on the prior art, as such would be obviousness-type support, and such does not supplant the need to demonstrate possession.

Applicant has done no more than assert that no new matter has been introduced. However, it incumbent on Applicant to demonstrate possession, and broad aversion does not supplant Applicant's duty.

Hence, the Artisan would not have understood Applicant to have been in possession of the claimed scope at the time of invention.

Claim Rejections - 35 USC § 112 - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods in which the vector contains a promoter operatively linked to a

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coding sequence of interest, does not reasonably provide enablement for any embodiment lacking a promoter and operatively-linked coding sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 73-75 encompass methods of making polypeptides. The methods require that a host cell be transfected with vector comprising SEQ ID NO: 1 and one of (i) an enhancer; (ii) a promoter; (iii) a coding sequence; or (iv) a functional fragment of (i) or (ii), and then culturing the cell under conditions to make the polypeptide. Claims 74 and 75 require an additional isolation step for the polypeptide and that the transfection be stable, respectively.

The first, and most important, aspect, is that the vector is not absolutely required to code for the polypeptide of interest. Further, and also important, is that the vector is not required to comprise an operatively linked promoter. However, as is taught throughout the specification, and is known in the Art, the vector must encode the polypeptide and requires an operatively linked promoter, so that the cell may make the polypeptide via standard expression mechanisms. Nothing is known in the Art of a cell which can replicate a protein, just by being transformed with a vector comprising any random sequences. Hence, for this aspect, the Artisan would have to perform undue experimentation to find those cell types which would replicate proteins from vectors which have transformed the cell.

Such experimentation is undue as it amounts to inventing the breadth of Applicant's claimed invention for Applicant. Hence, the claims lack an enabling disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-55, 57, 58, 62-64, 70, 71, 73, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,395,549 to Tuan, et al., Recillas-Targa, et al. (2002) Proceedings of the National Academy of Sciences, USA, 99(10) 6883-88), Chung, et al. (1997) Proceedings of the National Academy of Sciences, USA, 94: 575-80, and U.S. Patent No. 6,432,700 to Henderson, et al.

Tuan teaches integrating vectors comprising enhancers, insulators, and promoters to drive the expression of any gene of interest in animal cells (ABSTRACT). Further, it is taught to use barrier-function sequences to isolate the integrated vector from position effects in the chromatin to avoid silencing (e.g., Detailed Description of the Invention, paragraph 5). Hence, Tuan teaches that it is known in the Art to place barrier-function sequences on both sides of an integrating vector in order to protect it from silencing, and this can be used for the expression of desired transgenes. Further Tuan teaches the use of GFP coding sequences as a reporter for expression (e.g., paragraph preceding "Constructs and Vectors), and further to link the expression of such GFP to hCMV to obtain expression in cells (e.g., Figure 8), as it is well known that such promoters are widely active in many cell types (absent reason to believe otherwise, this is hCMV-IE1, as such is the standard utilized in the Art for constitutive expression). Hence, the Artisan would know that the use of a GFP coding sequence would allow

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quick identification of transformed cells, as is standard in the Art to identify the transformed and expressing cells.

Recillas-Targa teaches that the position protection effect of the chicken beta-globin insulator is located in a larger region encompassed by Applicant's SEQ ID NO: 1 (e.g., Figure 1), and is severable from the enhancer blocking activity (e.g., TITLE). Further, Recillas-Targa teaches that it is normal to utilize two copies of the position-effect on both sides of the vector provide for good isolation from position effects (e.g., p. 6885, col. 2, paragraph 3). Lastly, Recillas-Targa teaches minimization of domain sizes (e.g., whole article).

Chung teaches that the same insulator as Recillas-Targa is active in mammalian cells (e.g., p. 576, col. 2, paragraph 2).

Henderson teaches that it is optimal to minimize the size of the other components of the vector, in order to make more room for transgenes which are to be expressed (e.g., col. 17, paragraph 1).

Further, Official Notice is provided that polyA sequences are known in the Art for transcriptional processing, and typically used in the Art.

Hence, from this, the Artisan would be motivated to make an integrating vector, comprising two copies of SEQ ID NO 1 on each end of the integrating vector, with the normally-present base that Applicant has removed from the sequence, and further to comprise the CMV promoter driving expression of GFP. The Artisan would be so-motivated to provide the minimal sequence of the beta-globin barrier sequence of Recillas-Targa, and do so to express proteins in mammalian cells, as is taught in Chung. In addition, there is a reasonable expectation of success,

as the use of such barriers was known, the methods of minimization were known, and the methods of utilizing such to express proteins from integrated vectors was known.

However, such, in itself, does not make obvious the further deletion of the base which Applicant's SEQ ID NO: 1 is missing, from that of the known sequence of the chicken beta globin insulator/barrier sequence.

On the other hand, it is clear that the Artisan knew that the important sequences for the barrier functions were those regions that did not bind proteins (e.g., Recillas-Targa, DISCUSSION), and that intervening sequences were not known to be important. Moreover, Applicant's deleted base is within the intervening sequences (e.g., Chung, FIGURE 3, line 5 of the sequence, the penultimate "C" in such line, determined by comparison to Applicant's specification, FIGURE 1).

Hence, it would be obvious to further delete the "C" between the binding regions. The Artisan would have done so to further minimize the size the barrier region. Further the Artisan would have expected success, as such region was not bound by any proteins which cause the barrier effect.

Therefore, the Artisan would make these integrating vectors and transform mammalian cells with such vectors to express transgenes, including GFP for identification of those cells expressing the transgene. The Artisan would have expected success, as the methods were known in the Art.

Response to Argument – 103 – Tuan/Recillas-Targa/Chung/Henderson

Applicant's arguments of 11/17/08 have been fully considered but are not found persuasive.

Applicant argues broadly that the presently-claimed invention is non-obvious over the cited art (p. 8, paragraph 2).

Such is not persuasive. Specific reasoning and/or data is required to overcome the rejection, not broad attorney argument.

Applicant argues that Recillas-Targa does not teach that the core is not active in other cells (p. 9, paragraph 3).

Such is not persuasive. Chung is utilized to teach that the Artisan recognized the insulator was active in other cells. Moreover, of course the core must be active, otherwise the insulator would not be active.

Applicant argues that Recillas-Targa teaches several cores, and is limited to a 250 bp sequence, and hence, it does not teach the specific sequence size claimed.

Such is not persuasive. The claims are drawn to such sequence being the insulating sequence and do not exclude any other sequences, and in fact, as shown in the depending claims which comprise the sequence, necessarily comprise the sequence. Hence, even the larger sequences would encompass such smaller claimed sequence.

Applicant argues that they have unexpected levels of transfection and unexpected levels of protein production with their vectors, and hence, they are patentable over the Art (pp. 9-10, paragraph bridging).

Such is not persuasive. Applicant's comparison is compared to a non-insulator containing vector, not to the Recillas-Targa vector, and further, Applicant does not claim the increased activities, and hence no consideration of such activities is required in the first place.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-59, 62-67, 69, 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,395,549 to Tuan, et al., Recillas-Targa, et al. (2002) Proceedings of the National Academy of Sciences, USA, 99(10) 6883-88), Chung, et al. (1997) Proceedings of the National Academy of Sciences, USA, 94: 575-80, and U.S. Patent No. 6,432,700 to Henderson, et al. as applied to claims 52-55, 57, 58, 62-64, 69, 70, 71, 73, and 75 above, and further in view of Perlman, et al. (2003) The Journal of Clinical Endocrinology & Metabolism, 88(7): 3227-35 and Aldrich, et al. (1998) Cytotechnology, 28: 9-17.

As shown above, the Art teaches various claims, but does not teach the polypeptide of interest being FSH alpha and beta subunits, or the use of CHO cells, bicistronic vectors and the question of isolation has not been addressed.

On the other hand, Perlman teaches that CHO cells can be used to express FSH from vectors comprising the alpha and beta subunits (e.g., p. 3228, col. 1).

Aldrich teaches the use of bicistronic vectors for expression, which provide for reducing the time required to develop cell pools for protein expression (e.g., ABSTRACT).

Moreover, the Artisan would isolate the FSH for use (Official Notice).

Hence, it would be further obvious to transform CHO cells with such vectors carrying the alpha and beta subunits of FSH in a bicistronic vector. The Artisan would be motivated to do so

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in order to express and isolate FSH from the cells with reduced time to develop cell pools for protein expression. Moreover, the Artisan would have a reasonable expectation of success, as the cells were already known for expression of FSH and isolation techniques are known in the Art.

Response to Argument – 103 – Tuan/Recillas-Targa/Chung/Henderson/Perlman/Aldrich

Applicant's arguments of 11/17/08 have been fully considered but are not found persuasive.

Applicant argues broadly that the presently-claimed invention is non-obvious over the cited art (p. 8, paragraph 3).

Such is not persuasive. Specific reasoning and/or data is required to overcome the rejection, not broad attorney argument, and now Aldrich is added.

Arguments made which are applicable to rejections are answered in the base art rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-55, 57, 58, 61-64, 69, 70, 71, 73, and 75 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,395,549 to Tuan, et al., Recillas-Targa, et al. (2002) Proceedings of the National Academy of Sciences, USA, 99(10) 6883-88), Chung, et al. (1997) Proceedings of the National Academy of Sciences, USA, 94: 575-80, and U.S. Patent No.

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6,432,700 to Henderson, et al. as applied to claims 52-55, 57, 58, 62-64, 69, 70, 71, 73, and 75 above, and further in view of U.S. Patent No. 6,194,152 to Laus, et al.

As shown above, the Art teaches various claims, but does not teach the transgene for expressing thymidine kinase.

On the other hand, Laus teaches expression of thymidine kinase transgenes as a selectable marker in mammalian cells (e.g., section titled “c. Expression in Mammalian Systems”, paragraph 7).

Hence, it would be further obvious to modify the vectors to comprise the thymidine kinase transgene as a marker for mammalian cell expression. Moreover, the Artisan would have a reasonable expectation of success, as such markers were well known in the Art.

Response to Argument – 103 – Tuan/Recillas-Targa/Chung/Henderson/Laus

Applicant's arguments of 11/17/08 have been fully considered but are not found persuasive.

Applicant argues broadly that the presently-claimed invention is non-obvious over the cited art (p. 8-9, paragraph bridging).

Such is not persuasive. Specific reasoning and/or data is required to overcome the rejection, not broad attorney argument.

Arguments made which are applicable to rejections are answered in the base art rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-55, 56, 57, 58, 62-66, 68-74, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,395,549 to Tuan, et al., Recillas-Targa, et al. (2002) Proceedings of the National Academy of Sciences, USA, 99(10) 6883-88), Chung, et al. (1997) Proceedings of the National Academy of Sciences, USA, 94: 575-80, and U.S. Patent No. 6,432,700 to Henderson, et al. as applied to claims 52-55, 57, 58, 62-64, 69, 70, 71, 73, and 75 above, and further in view of U.S. Patent No. 6,113,898 to Anderson, et al. and Aldrich, et al. (1998) Cytotechnology, 28: 9-17.

As shown above, the Art teaches various claims, but does not teach the use of CHO cells, or the expression of the heavy and light chains of an immunoglobulin nor the use of bicistronic vectors, or humanized sequences.

On the other hand, Anderson teaches CHO cells being transformed to express the heavy and light chains of antibodies to the human B7.1 and/or B7.2 antigens (e.g., Summary of the Invention, penultimate paragraph).

Aldrich teaches the use of bicistronic vectors for expression, which provide for reducing the time required to develop cell pools for protein expression (e.g., ABSTRACT).

Moreover, the Artisan would isolate the Immunoglobulin for use (Official Notice).

Hence, at the time of invention, it would have been obvious to further modify the vector to comprise the coding sequences of the heavy and light chains of such antibodies in a bicistronic vector of aldrich. The Artisan would do so in order to express such in CHO cells, isolate the

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proteins, and reduce the time to develop cell pools for protein expression. Moreover, there is a reasonable expectation of success, as Anderson teaches such expression.

Response to Argument – 103 – Tuan/Recillas-Targa/Chung/Henderson/Anderson/Aldrich

Applicant's arguments of 11/17/08 have been fully considered but are not found persuasive.

Applicant argues broadly that the presently-claimed invention is non-obvious over the cited art (p. 9, paragraph 2).

Such is not persuasive. Specific reasoning and/or data is required to overcome the rejection, not broad attorney argument, and Aldrich is now added.

Arguments made which are applicable to rejections are answered in the base art rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-55, 56, 57, 58, 62-66, 68-74, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,395,549 to Tuan, et al., Recillas-Targa, et al. (2002) Proceedings of the National Academy of Sciences, USA, 99(10) 6883-88), Chung, et al. (1997) Proceedings of the National Academy of Sciences, USA, 94: 575-80, and U.S. Patent No. 6,432,700 to Henderson, et al.; U.S. Patent No. 6,113,898 to Anderson, et al. and Aldrich, et al.

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(1998) Cytotechnology, 28: 9-17 as applied to claim 52-55, 56, 57, 58, 62-66, 68-74, and 75 above, and further in view of U.S. Patent No. 6,632,927 to Adair, et al.

As shown above, the various aspects are obvious, except the use of humanized sequences for a chain of the antibody.

On the other hand, Adair teaches humanized antibody sequences for expression in cells (e.g., ABSTRACT).

Hence, it would be obvious to substitute Adair's humanized sequences. The Artisan would do so to produce the humanized antibodies taught by Adair. Moreover, the Artisan would have a reasonable expectation of success, as Adair teaches such.

Response to Argument – 103 – Tuan/Recillas-

Targa/Chung/Henderson/Anderson/Aldrich/Adair

Applicant's arguments of 11/17/08 have been fully considered but are not found persuasive.

Applicant argues broadly that the presently-claimed invention is non-obvious over the cited art (p. 8, paragraph 2).

Such is not persuasive. Specific reasoning and/or data is required to overcome the rejection, not broad attorney argument, and Aldrich and Adair are now added.

Arguments made which are applicable to rejections are answered in the base art rejection.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633